UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, and the DISTRICT OF COLUMBIA *ex rel.* URI BASSAN,

Plaintiffs,

v.

OMNICARE, INC.,

Defendant.

UNITED STATES OF AMERICA,

Plaintiff,

v.

OMNICARE, INC. and CVS HEALTH CORP.,

Defendants.

Case No. 15-CV-4179 (CM)

REPLY IN SUPPORT OF MOTIONS TO DISMISS GOVERNMENT'S
COMPLAINT-IN-INTERVENTION BY OMNICARE AND CVS

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TABLE OF CONTENTS

| 1. | THE COMPLAINT DOES NOT STATE A CLAIM UNDER THE FALSE CLAIMS ACT | | 2 |
|------|---|---|----|
| | A. | The Complaint Does Not Sufficiently Plead that Omnicare Submitted "False or Fraudulent" Claims. | 2 |
| | | 1. The Complaint Does Not State a Claim for "Legal Falsity." | 2 |
| | | 2. The Government Does Not State a Claim for "Factual Falsity." | 9 |
| | B. | The Complaint Does Not Sufficiently Plead Particular False Claims | 11 |
| | C. | The Complaint Does Not Sufficiently Plead that Omnicare Acted "Knowingly." | 14 |
| II. | THE (| COMPLAINT DOES NOT STATE A CLAIM AGAINST CVS | 18 |
| III. | THE (| COMPLAINT DOES NOT STATE A "REVERSE" FALSE CLAIM | 21 |
| IV. | | COMPLAINT DOES NOT STATE A CLAIM FOR UNJUST CHMENT OR PAYMENT BY MISTAKE | 23 |
| CON | CLUSIC | ON | 25 |
| | | | |

TABLE OF AUTHORITIES

CASES

| Alexander v. Sandoval, 532 U.S. 275 (2001)25 |
|---|
| Am. Elec. Power Co. v. Connecticut, 564 U.S. 410 (2011) |
| Brown v. Kay, 889 F. Supp. 2d 468 (S.D.N.Y. 2012)22 |
| Erie R. Co. v. Tompkins, 304 U.S. 64 (1938)23 |
| Nelson v. MillerCoors, LLC, 246 F. Supp. 3d 666 (E.D.N.Y. 2017)22 |
| Palatkevich v. Choupak, 2014 WL 1509236 (S.D.N.Y. Jan. 24, 2014) |
| Sturgeon v. Pharmerica Corp., 438 F. Supp. 3d 246 (E.D. Pa. 2020) |
| Texas Industries, Inc. v. Radcliff Materials, Inc., 451 U.S. 630 (1981)24 |
| United States ex rel. Chin v. CVS Pharmacy, Inc., 2017 WL 4174416 (C.D. Cal. Aug. 15, 2017) |
| United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc., 865 F.3d 71 (2d Cir. 2017) |
| United States ex rel. Crennen v. Dell Mktg. LP, 711 F. Supp. 2d 157 (D. Mass. 2010)14 |
| United States ex rel. Crews v. NCS Healthcare, 460 F.3d 853 (7th Cir. 2006) |
| United States ex rel. Davern v. Hoovestol, Inc., 2015 WL 6872427 (W.D.N.Y. Nov. 9, 2015)21 |
| United States ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Grp., 298 F. Supp. 2d 91 (D.D.C. 2004) |
| United States ex rel. Escobar v. Universal Health Servs., 780 F.3d 504 (1st Cir. 2015)13 |
| United States ex rel. Forcier v. Comput. Scis. Corp., 183 F. Supp. 3d 510 (S.D.N.Y. 2016) |
| United States ex rel. Forcier v. Comput. Scis. Corp., 2017 WL 3616665 (S.D.N.Y. Aug. 10, 2017) |
| United States ex rel. Gelbman v. City of New York, 790 F. App'x 244 (2d Cir. 2019)14 |
| United States ex rel. Glass v. Medtronic. Inc., 957 F 2d 605 (8th Cir. 1992) |

| (7th Cir. 2014) | 12 |
|---|--------|
| United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C., 318 F. Supp. 3d 680 (S.D.N.Y. 2018) | .6, 15 |
| United States ex rel. Hefner v. Hackensack Univ. Med. Ctr., 495 F.3d 103 (3d Cir. 2007) | 16 |
| United States ex rel. Hobbs v. MedQuest Assocs., Inc., 711 F.3d 707 (6th Cir. 2013) | 5 |
| United States ex rel. Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25 (D.D.C. 2007) | 19 |
| United States ex rel. Jorgenson v. Alan Ritchey, Inc., 2007 WL 1287932 (W.D. Wash. Apr. 27, 2007)1 | 2, 17 |
| United States ex rel. Kester v. Novartis Pharm. Corp., 2014 WL 4401275 (S.D.N.Y. Sept. 4, 2014) | 25 |
| United States ex rel. Kester v. Novartis Pharms. Corp., 2015 WL 109934 (S.D.N.Y. Jan. 6, 2015) | 13 |
| United States ex rel. Kester v. Novartis Pharms. Corp., 23 F. Supp. 3d 242 (S.D.N.Y. 2014) | 0, 11 |
| United States ex rel. Kester v. Novartis Pharms. Corp., 41 F. Supp. 3d 323 (S.D.N.Y. 2014) | 5 |
| United States ex rel. Kirk v. Schindler Elevator Corp., 130 F. Supp. 3d 866 (S.D.N.Y. 2015) | 16 |
| United States ex rel. Kolchinsky v. Moody's Corp., 2017 WL 3841866 (S.D.N.Y. Sept. 1, 2017) | 11 |
| United States ex rel. Manion v. St. Luke's Reg'l Med. Ctr., Ltd., 2008 WL 906022 (D. Idaho Mar. 31, 2008) | 13 |
| United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc., 2018 WL 4539684 (D. Mass. Sept. 21, 2018) | 20 |
| United States ex rel. Petras v. Simparel, Inc., 857 F.3d 497 (3d Cir. 2017) | 22 |
| United States ex rel. Seal 1 v. Lockheed Martin Corp., 429 F. App'x 818 (11th Cir. 2011) (per curiam) | 13 |
| United States ex rel. Taylor v. Gabelli, 345 F. Supp. 2d 313 (S.D.N.Y. 2004) | 22 |
| United States ex rel. Tessler v. City of New York, 712 F. App'x 27 (2d Cir. 2017) | 14 |

| No. 11 v. City of Chicago, 2014 WL 6306582 (N.D. Ill. Nov. 12, 2014) | |
|--|----------------|
| United States v. AMC Ent., Inc., 549 F.3d 760 (9th Cir. 2008) | 8 |
| United States v. Bestfoods, 524 U.S. 51 (1998) | 18 |
| United States v. Buckley, 2005 WL 164287 (D. Mass. Jan. 25, 2005) | 25 |
| United States v. Comstor Corp., 308 F. Supp. 3d 56 (D.D.C. 2018) | 12 |
| United States v. Exec. Health Res., Inc., 196 F. Supp. 3d 477 (E.D. Pa. 2016) | 20 |
| United States v. Gen. Dynamics Corp., 19 F.3d 770 (2d Cir. 1994) | 24 |
| United States v. Hydroaire, Inc., 1995 WL 86733 (N.D. III. Feb. 27, 1995) | 25 |
| United States v. Ihenacho, 716 F.3d 266 (1st Cir. 2013) | 3 |
| United States v. Job Res. for Disabled, 2000 WL 562444 (N.D. Ill. May 9, 2000) | 25 |
| United States v. Kennedy, 738 F.2d 584 (3d Cir. 1984) | 23 |
| United States v. Kimbell Foods, Inc., 440 U.S. 715 (1979) | 23 |
| United States v. Kinetic Concepts, Inc., 2017 WL 2713730 (C.D. Cal. Mar. 6, 2017) | 7)22 |
| United States v. Lahey Clinic Hosp., Inc., 399 F.3d 1 (1st Cir. 2005) | 24 |
| United States v. Little Lake Misere Land Co., 412 U.S. 580 (1973) | 24 |
| United States v. McKesson Corp., 2019 WL 438357 (E.D.N.Y. Feb. 4, 2019) | 21 |
| United States v. Mount Sinai Hosp., 256 F. Supp. 3d 443 (S.D.N.Y. 2017) | 21 |
| United States v. N. Am. Health Care, Inc., 173 F. Supp. 3d 943 (N.D. Cal. 2016) | 14 |
| United States v. Oz, 2016 WL 1183041 (D. Minn. Mar. 28, 2016) | 5 |
| United States v. Prabhu, 442 F. Supp. 2d 1008 (D. Nev. 2006) | 8 |
| United States v. Riccio, 43 F. Supp. 3d 301 (S.D.N.Y. 2014) | 3 |
| United States v. Teva Pharms. USA, Inc., 2016 WL 750720 (S.D.N.Y. Feb. 22, 2016) | 10, 13, 19, 20 |
| United States v. Vector Corp., 1994 U.S. Dist. LEXIS 21330 (N.D. Iowa Apr. 14, 1994) | 25 |

| United States v. Wurts, 303 U.S. 414 (1938) | 24 |
|---|--------|
| Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016) | 15 |
| OTHER AUTHORITIES | |
| 42 C.F.R. § 405.371 | 24 |
| 42 C.F.R. § 405.373 | 24 |
| 42 C.F.R. § 405.375 | 24 |
| 42 C.F.R. § 405.1803 | 24 |
| 42 C.F.R. § 423.100 | 3, 5 |
| 42 C.F.R § 423.104(h) | 5 |
| 42 C.F.R. § 440.120(a) | 5 |
| 76 Fed. Reg. 63,018, 63,059 (Oct. 11, 2011) | 4 |
| 21 U.S.C. § 353(b)(1) | 3 |
| 21 U.S.C. § 841(h) | 3 |
| 31 U.S.C. § 3729(a)(1)(A) | 14 |
| 31 U.S.C. § 3729(a)(1)(B) | 14 |
| 31 U.S.C. § 3729(a)(1)(G) | 21, 22 |
| 31 U.S.C. § 3729(b)(1) | 11 |
| 31 U.S.C. § 3733 | 14 |
| 42 U.S.C. § 1320a-7k(d)(4)(B) | 23 |
| 42 U.S.C. § 1395w-102(e) | 3 |
| 42 U.S.C. § 1396d(a)(12) | 5 |
| Dep't of Justice, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan. 25, 2018), https://www.justice.gov/opa/press-release/file/1028756/download | Л |
| Fed. R. Civ. P. 8. | |
| Fed. R. Civ. P. 9(b) | |

ν

Case 1:15-cv-04179-CM-VF Document 86 Filed 08/13/20 Page 8 of 34

| Fed. R. Evid. 407 | 17 |
|---|----|
| Ind. Code Ann. § 25-26-13-2 | 8 |
| John T. Boese, Civil False Claims and Qui Tam Actions § 2.01 (4th ed. 2020) | 22 |
| John T. Boese, Civil False Claims and Qui Tam Actions § 2.03 (4th ed. 2020) | 4 |
| Wyo. Admin. Code 059.0001.15 § 4 | 9 |

The Government brought this wide-ranging False Claims Act case against Omnicare based on three fundamental misunderstandings of the long-term-care industry. First, the Government contended that long-term-care facilities can be neatly classified into Skilled Nursing Facilities ("SNFs"), which involve medical oversight of residents' needs, and Assisted Living Facilities ("ALFs"), which span the range of all other facilities. In fact, long-term-care facilities exist on a spectrum of care, and many of what the Government calls "ALFs" provide significant medical oversight to residents. Second, the Government contended that the Medicare, Medicaid, and Tricare laws incorporate state-law requirements governing the documentation of prescriptions. But Medicaid and Tricare do not incorporate state-law requirements, and Medicare did not do so until 2013. Third, the Government contended that those state laws uniformly prohibit the use of medication orders—physician orders for medication that do not include a set quantity or number of refills—outside of SNFs. Yet the vast majority of states mentioned in the Government's Complaint had laws that explicitly permit the use of medication orders in some or all of the facilities that the Government calls "ALFs." The Government's Opposition fails to defend those premises, and its pivot to new, unpleaded theories of liability is procedurally improper and substantively meritless. The Government's claims should be dismissed for failing to sufficiently allege that Omnicare submitted "false" claims.

The Government's claims also fail other pleading requirements. They are vastly overbroad, extending without the specificity required by Rule 9(b) to (a) a distinct computer-dispensing system used at distinct pharmacies, (b) 4 additional years, and (c) different federal healthcare programs. The Government also fails to plead scienter, resting on a theory that Omnicare intentionally designed its computer systems to fail, which is not supported by a single allegation. And the Government's follow-on claims for "reverse" false claims, unjust

enrichment, and payment by mistake all fail for these reasons and other, claim-specific reasons.

I. THE COMPLAINT DOES NOT STATE A CLAIM UNDER THE FALSE CLAIMS ACT

The Opposition advances new, unpleaded theories. This attempt to amend the Complaint is not only procedurally improper, it fails to cure the defects in the Complaint's original theories—and, in fact, creates new ones. The affirmative-FCA claims should be dismissed for three reasons: *First*, the Complaint does not allege facts showing that any prescription claim was "false," whether under the Complaint's "legal falsity" theories or the newly concocted "factual falsity" theory. *Second*, the Complaint lacks the particularity demanded by Rule 9(b). *Third*, the Complaint does not sufficiently allege that Omnicare acted "knowingly."

A. The Complaint Does Not Sufficiently Plead that Omnicare Submitted "False or Fraudulent" Claims.

The Complaint is premised on the propositions that (a) Medicare Part D, Medicaid, and Tricare incorporate state-law requirements and (b) those state laws uniformly prohibit the use of medication orders outside of SNFs. Omnicare's motion to dismiss undercuts both of these premises, but the Government hardly defends them. Its scattershot citation of federal laws includes none that supports its theory of nationwide falsity. And the Government barely responds to Omnicare's argument that the vast majority of states mentioned in the Complaint have laws that specifically permit the conduct the Government claims was illegal. Indeed, the Government now claims that "state laws regulating prescriptions and drug orders in different long-term care settings are largely irrelevant." Dkt. No. 81 (Gov't Opp'n) 20 ("Opp'n").

In its retreat from the theory of liability on which the Complaint was premised, the Government purports to substitute an entirely new theory of "factual falsity." That theory is both unpled and legally misguided, and the Court should reject it.

1. The Complaint Does Not State a Claim for "Legal Falsity."

a. The Government's Nationwide Theory of Falsity Is Baseless.

The Complaint's first premise is that, at all times, Medicare Part D, Medicaid, and Tricare contained legal provisions barring reimbursement where the pharmacy did not follow all state regulatory requirements concerning prescription documentation. *See* Gov't Compl. ¶¶ 29, 45, 239. The Complaint cited 42 C.F.R. § 423.100 as allegedly imposing this requirement, Gov't Compl. ¶ 89, but the Opposition does not dispute that this regulation applies to Medicare Part D only and did not come into effect until January 1, 2013. *See* Dkt. No. 72 (Mot. to Dismiss Gov't Compl.) 4–5, 10 ("Mot."). Because the Government "fails to point to a federal regulatory requirement" supporting its theory of falsity, *United States ex rel. Crews v. NCS Healthcare*, 460 F.3d 853, 858 (7th Cir. 2006), the Complaint's claims based on Medicaid, Tricare, and pre-2013 Medicare prescriptions should be dismissed.¹ This is not "silly." Opp'n 17. Omnicare is holding the Government to the claim it pleaded (and the Government comes up short).

1. <u>Medicare Part D</u>. The Government does not identify any pre-2013 provision regarding the scope of prescription coverage under Medicare Part D. The Government nods at 42 U.S.C. § 1395w-102(e), but that merely states that a "covered part D drug" is one that "may be dispensed only upon a prescription," with no reference to any aspect of state law or prescription-documentation rules. Opp'n 17. The Government also relies on a 2011 Notice of Proposed Rulemaking, in which CMS stated its *belief* regarding the scope of Medicare Part D

¹ In its Opposition, the Government tosses out a few other legal provisions, but none supports its theory, and most have nothing to do with Medicare, Medicaid, Tricare, or state prescription-documentation laws. *See* 21 U.S.C. § 353(b)(1) (provision of Controlled Substances Act with no reference to Medicare, Medicaid, Tricare, or state prescription-documentation laws); *United States v. Riccio*, 43 F. Supp. 3d 301, 308 (S.D.N.Y. 2014) (interpreting federal statute barring the dispensing of controlled substances over the internet, 21 U.S.C. § 841(h)); *United States v. Ihenacho*, 716 F.3d 266, 270 (1st Cir. 2013) (same). Nor does a decision about a pharmacy routinely giving patients drugs that were entirely different from what they had been prescribed have anything to do with the nuances of state prescription-documentation law at issue here. *See Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 275–76 (E.D. Pa. 2020).

coverage. *See* Opp'n 16–17 (citing 76 Fed. Reg. 63,018, 63,059 (Oct. 11, 2011)). But the Government fails to mention the next sentence of the Proposed Rule, in which CMS admitted it was referring to an unwritten "policy" that it wished to "codify" "to remove any doubt as to the appropriate source of law to consult when determining whether a prescription is valid." 76 Fed. Reg. 63,018, 63,059 (Oct. 11, 2011). The Government cannot seriously contend that an FCA claim arises from alleged violations of an uncodified "policy" about which there was "doubt." *See* 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.03 (4th ed. 2020) ("[T]o the extent that FCA allegations turn on noncompliance with any agency guidance documents, rather than statutory or regulatory requirements, they should not be considered a basis for a false certification claim under the FCA."). Indeed, the Department of Justice has sworn off basing FCA cases on alleged "noncompliance with guidance documents." Dep't of Justice, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases 2 (Jan. 25, 2018).²

Nor does the Government allege that Omnicare made any express or implied certification of compliance with any law that could support its Medicare claims. The Government does not argue an "implied" certification theory as to Medicare Part D, *see* Opp'n 16, and it agrees that express certification "arises where a government program requires participants to explicitly state that they have complied with *certain* statutes or requirements." *Id.* at 15 (emphasis added). But the Government does not argue that Omnicare ever certified compliance with *any* particular Medicare law or regulation. *See id.* at 15–16. Instead, the Government relies on Omnicare's alleged certification of compliance with "*all* applicable federal laws." Gov't Compl. ¶ 38; *see* Opp'n 15–16. It is questionable whether such a "general certification of compliance" could ever give rise to express-certification liability. *United States ex rel. Forcier v. Comput. Scis. Corp.*,

² https://www.justice.gov/opa/press-release/file/1028756/download.

183 F. Supp. 3d 510, 526 (S.D.N.Y. 2016) (alterations omitted) (no express certification arising from assertion of the truth of "all statements").³ Regardless, until 2013, there was no "federal law" that was even arguably "applicable." And the Government admits that Omnicare made no certification of compliance with *any* state law under Medicare Part D. *See* Opp'n 15–16.

2. *Medicaid.* The Government admits that the regulations on which its Complaint was premised, 42 C.F.R §§ 423.100, 423.104(h), do not apply outside of Medicare Part D. See Opp'n 16–17. It does not dispute that the Medicaid provision it previously mentioned, 42 U.S.C. § 1396d(a)(12), says nothing about incorporating state laws or their prescription-documentation rules. See Opp'n 17. The Government briefly cites 42 C.F.R. § 440.120(a), but that regulation says nothing about state-law prescription requirements, and instead defines the scope of "professional practice" for the physicians who write prescriptions. The Government then baldly asserts that Omnicare "should know" that Medicaid meant to incorporate these aspects of state prescription-documentation law. Opp'n 17. The Government's sole support for this proposition is a 2016 decision rejecting a vagueness challenge to a provision of the Controlled Substances Act banning dispensing of controlled substances over the internet. See United States v. Oz, 2016 WL 1183041, at *10 (D. Minn. Mar. 28, 2016). That decision had nothing to do with Medicaid or state laws regarding prescription documentation and it involved a statute not at issue here. In any event, the Government cannot premise a fraud claim on uncodified beliefs about what Omnicare "should know." See United States ex rel. Hobbs v. MedQuest Assocs., Inc., 711 F.3d 707, 718–19 (6th Cir. 2013) ("[T]he FCA does not impose liability for providers' failure to

³ The certifications here make no mention of the prescription-documentation provisions on which the Government premises its case and are therefore distinct from more specific certifications of compliance. *See, e.g., United States ex rel. Kester v. Novartis Pharms. Corp.*, 41 F. Supp. 3d 323, 337 (S.D.N.Y. 2014) (Anti-Kickback Statute case involving certifications of compliance with laws "designed to prevent fraud, waste, and abuse," including "the anti-kickback statute").

anticipate needs of the program that have not been promulgated in regulations.").

The Government also fails to plead a plausible "certification" of legal compliance that could support its Medicaid claims. It does not argue an "implied" certification theory. *See* Opp'n 16. Nor does it contend that Omnicare ever expressly certified compliance with *any* particular Medicaid law or regulation, or with any particular state prescription law. *See id.* at 15–16. Instead, the Government rests on Omnicare's alleged general certification of compliance with all "applicable federal and state laws and regulations." Gov't Compl. ¶ 50; *see* Opp'n 16. But the Government does not identify *any* certification in *any* state, despite admitting there are "variations among the states." Gov't Compl. ¶ 49. Regardless, such a "general certification of compliance" should not give rise to express-certification liability, *Forcier*, 183 F. Supp. 3d at 526 (alterations omitted), particularly where, as discussed above, the Government cannot point to any "applicable" law or regulation that supports its theory of falsity in the first place.

3. Tricare. The Government does not defend its Tricare allegation at all. It does not purport to identify a single legal provision that applies to Tricare, see Opp'n 16, and cites only paragraphs of its Complaint that expressly address Medicare Part D and Medicaid. See Gov't Compl. ¶¶ 240–246. The Government also disclaims any express-certification theory as to Tricare. See Opp'n 16. And although it briefly suggests that it pleads an implied false certification theory as to Tricare, see id., such a theory applies only if "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements . . . render[ing] the . . . representations misleading." United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C., 318 F. Supp. 3d 680, 699 (S.D.N.Y.), reconsideration denied, 319 F. Supp. 3d 747 (S.D.N.Y. 2018) (alterations in original) (quoting Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1999 (2016)).

But the Government did not identify any qualifying "representation[]" made by Omnicare, Mot. 11, nor even respond to Omnicare's argument.

- Finding no federal-law grounding for its theory of legal falsity, the Government 4. briefly purports to reinvent its claim, asserting that the case is actually just about the use of "documents that do not constitute valid prescriptions under any federal or state definition." Opp'n 20. "[S]tate laws regulating prescriptions and drug orders in different long-term care settings," the Government now asserts, "are largely irrelevant" to the case. *Id.* That is a remarkable departure from the Government's Complaint, which focused on the use of medication orders, the fact that they are generally permissible for use in SNFs, their alleged impermissibility in ALFs, and Omnicare's computer systems for processing those orders. The Court should reject the Government's attempt to add this claim in an opposition to a motion to dismiss. See Palatkevich v. Choupak, 2014 WL 1509236, at *10 (S.D.N.Y. Jan. 24, 2014) (plaintiffs "may not amend a pleading through an opposition brief"). But even if the Complaint were stretched to create an entirely new FCA claim, it makes no allegations to support this new "bad documents" theory of falsity. As just one example, despite purporting to be a theory of "legal" falsity, the cited paragraphs make no mention of any federal or state law that the Government could claim was violated, or any certification of compliance with such a law.
 - b. Many States Permitted Omnicare To Dispense to Long-Term-Care Facilities Based on Medication Orders Without a Defined Number of Refills or Total Quantity.

The second premise underlying the Complaint is that, at all times, each state uniformly barred all long-term-care facilities other than SNFs from utilizing medication orders that do not specify the total quantity prescribed or number of refills. *See* Gov't Compl. ¶¶ 89–95, 99. The Government admitted that states generally allow the use of medication orders when dispensing to residents of SNFs, *id.* ¶ 99, but claimed the opposite was true with respect to all other long-term-

care facilities. In its motion to dismiss, Omnicare analyzed state laws and explained that "many states do not draw *any* line between SNFs and other long-term-care facilities for purposes of these prescription documentation guidelines" and instead allow medication orders in many facilities the Government calls "ALFs." Mot. 11 (emphasis added); *id.* at 5–6, 11–14, Ex. 1.

The Government claims that Omnicare's analysis of state law is "misleading," Opp'n 20, but its sole response to that analysis is to make inaccurate arguments about the laws of just two states—Indiana and Wyoming. The Government thereby concedes that a fundamental premise of its case is defective in the vast majority of the states mentioned in its Complaint. See United States ex rel. Glass v. Medtronic, Inc., 957 F.2d 605, 608 (8th Cir. 1992) (where defendant's actions were "proper" under the cited law, the corresponding claims were "not false or fraudulent"); accord United States v. Prabhu, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006). Nor can the Government avoid this by pointing to alleged beliefs of a few Omnicare employees, who stated general rules of thumb and did not purport to interpret any specific legal provision. See Opp'n 18–20; Mot. 6 n.3. Subjective individual beliefs cannot dictate the interpretation of any law. See United States v. AMC Ent., Inc., 549 F.3d 760, 769 (9th Cir. 2008).

Even as to Indiana and Wyoming, the Government misconstrues the law. In Indiana, the Government quotes a statutory requirement that a drug order specify "the amount to be dispensed either in quantity or days," Opp'n 21 (emphasis and citation omitted), but minimizes the statute's caveat that this is not required where "specified by individual institution policy or guideline." Ind. Code Ann. § 25-26-13-2. Where such drug orders are "specified by individual institution policy or guideline," they may be used in a range of long-term-care facilities. *See id.* §§ 25-26-

⁴ To the extent the Government intended to bring a claim related to the laws of states that are not even mentioned in the Complaint, *see* Opp'n 20 n.3, it has not alleged one.

13-2, 16-18-2-161, 16-18-2-167(a). As for Wyoming, state law allows the use of medication orders in any "LTCF." Wyo. Admin. Code 059.0001.15 § 4. That term does not include Wyoming "assisted living facilities," but it expressly includes much more than the SNFs to which the Government would limit medication orders. *See id.* (covering any "intermediate care nursing . . . home, board and care home, or any resident behavioral health facility subject to regulation and licensure by the department of health"). Both states contradict the Government's theory that medication orders are permitted in SNFs only, and that every other type of long-term-care facility in existence can be categorized as an ALF in which medication orders are never permitted.

Nor can the Government save its defective theory by arguing that a handful of states separately impose time limits on the use of medication orders. *See* Opp'n 21–22. Such a claim is far narrower than the Government's allegations that all medication orders were invalid in all states at all times. Regardless, the Government has no response to Omnicare's argument that continuing medication orders are simply different from the traditional prescriptions governed by the alleged time limits. *See* Mot. 13. By definition, a medication order is renewed each time a doctor reviews a patient's chart and it therefore does not expire in the way a traditional prescription does. *See id.* In any event, the Government does not respond to Omnicare's state-law citations reflecting that many states allow the use of even traditional prescriptions for a longer time period than the Government alleges. *See id.*; Opp'n 21.

2. The Government Does Not State a Claim for "Factual Falsity."

Facing fundamental defects with the legal-falsity theories on which the Complaint was premised, the Government now argues for a different basis of FCA liability: factual falsity. This

⁵ Notably, not a single facility the Government claims was a "rollover facility" forming the basis of its claim is located in Wyoming. *See* Compl. Exs. 1, 2.

theory does not appear in the Complaint and contradicts its factual allegations.

As the Government's own authority describes, "factual falsity is reserved for 'straightforward' frauds in which a claim for payment to the Government describes the services provided in a manner that differs from what was actually provided." *Forcier*, 183 F. Supp. 3d at 527–28. "In other words, the party 'bills for something it did not provide." *United States v. Teva Pharms. USA, Inc.*, 2016 WL 750720, at *19 (S.D.N.Y. Feb. 22, 2016) (citation omitted). Here, the Government does not "allege that any patient ever received a medication that was not actually needed." Mot. 7. And the Government makes no allegation that Omnicare dispensed anything other than the specific medication the patient required. *See United States ex rel. Kester v. Novartis Pharms. Corp.*, 23 F. Supp. 3d 242, 262 (S.D.N.Y. 2014) ("easily dispos[ing]" of a factual falsity theory where "[t]he Government does not assert that any of the claims submitted by the pharmacies misrepresented that [specific drugs were] actually dispensed to a patient").

The Government does not plead a single example of any alleged submission of inaccurate data fields regarding any prescription. It nevertheless insists that Omnicare must have reported inaccurate information about the prescription claims it submitted—namely the doctor's name, the form the prescription took, the number of refills and prior fills, whether the prescription was reimbursable, and the date the prescription was written. But the only thing that was "inaccurate" about those claims under the Government's theory is that Omnicare (allegedly) was required to "obtain[] valid new prescriptions" and had not done so. Opp'n 22. This is just a repackaging of the Government's theory of legal falsity. If state law did *not* require Omnicare to obtain a new prescription, then the information the Government cites was accurate.

Even if the Government could bring a factual-falsity theory, it cannot do so in an Opposition to a motion to dismiss. *See Palatkevich*, 2014 WL 1509236, at *10. Nor can the

handful of allegations in the Complaint the Government cites be construed as plausibly having brought a separate FCA claim alleging factual falsity. A theory of factual falsity must allege that the submission of false claims was done "knowingly," 31 U.S.C. § 3729(b)(1), but the Government makes no allegation regarding Omnicare's alleged knowledge of the specific contents of prescription data fields being submitted to the Government for payment. A factual-falsity theory must also include allegations that "the misrepresentation must [have been] material to the other party's course of action," *United States ex rel. Forcier v. Comput. Scis. Corp.*, 2017 WL 3616665, at *7 (S.D.N.Y. Aug. 10, 2017) (alteration in original), but the Government pleads nothing to suggest that the specific data fields it claims were inaccurate would have been "material" to any reimbursement decision by Medicare Part D, Medicaid, or Tricare. And the Government must plead a factual-falsity theory with particularity under Rule 9(b), *United States ex rel. Kolchinsky v. Moody's Corp.*, 2017 WL 3841866, at *3 (S.D.N.Y. Sept. 1, 2017), but it has not alleged even one example of the submission of inaccurate data fields. The Government's late-breaking factual-falsity theory should be rejected for all of these reasons.

B. The Complaint Does Not Sufficiently Plead Particular False Claims.

Even if the Government had articulated a viable theory of "falsity," its claim is vastly overbroad because it does not "plead with particularity that false claims were actually submitted to the government," *Kester*, 23 F. Supp. 3d at 252, for many of its theories. The Government cannot proceed on these theories, as the Second Circuit has made clear that a party that "can identify examples of actual claims must do so at the pleading stage." *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017).

1. The Government does not dispute that it has not pleaded a single claim related to its Oasis Theory, which asserts that particular computer defects were present in a distinct computer dispensing system, Oasis. *See* Opp'n 25–26. The Government contends that the facts

it alleged as to a different Omnicare computer-dispensing system, OmniDX, somehow suffice to prove fraud in the design of the Oasis system. See id. at 26. But Omnicare's two computerdispensing systems are wholly separate: A pharmacy uses one or the other, and approximately 40% of Omnicare pharmacies use Oasis. See Gov't Compl. ¶ 121. The Government asks the Court to "accept[]... that a defendant violating the FCA in one location [OmniDX] was engaging in the same conduct in another location [Oasis]." Opp'n 27 (citation omitted). But the Government is not alleging "the same conduct"; rather, it alleges that distinct pharmacies used a distinct computer system with distinct alleged defects to cause the submission of an entirely separate set of allegedly false claims. And even if the Government were alleging "the same conduct" in different locations, "alleged fraudulent activity at one plant does not constitute an allegation for a different plant." United States ex rel. Jorgenson v. Alan Ritchey, Inc., 2007 WL 1287932, at *3 (W.D. Wash. Apr. 27, 2007); see also, e.g., United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc., 772 F.3d 1102, 1108 (7th Cir. 2014) (dismissing one theory of fraud where the relator made no allegation to support his alleged knowledge of conduct at "a large number of pharmacies scattered over a number of states" where he was just aware of conduct in a single location).

2. The Government also does not dispute that although its claim spans the years 2010–2018, it did not plead the submission of any claim, under any theory of fraud, by any pharmacy, from 2010–2011 or 2017–2018. *See* Opp'n 27–28. In doubling the timeframe of its Complaint without alleging a single false claim, the Government brushes aside Omnicare's legal authority as involving complete failures to allege a fraudulent scheme. *See id.* at 27. In fact, those cases made clear that the relators there, like the Government here, failed their fundamental obligation to give "specific examples" that "cover the relevant time period." *United States v.*

Comstor Corp., 308 F. Supp. 3d 56, 92 (D.D.C. 2018); see also United States ex rel. Seal 1 v. Lockheed Martin Corp., 429 F. App'x 818, 820 (11th Cir. 2011) (per curiam) (engaging in a Rule 9(b) analysis as to distinct time periods of the alleged scheme and affirming the dismissal of a portion of claim relating to four-year period in which a relator "does not allege the amount of the claims, the number of claims presented nor dates on when such claims were made").⁶

The Government also does not contest that it did not identify a single Medicaid or Tricare claim submitted pursuant to any of its theories. *See* Opp'n 28–29. Omnicare recognizes that this Court has found in other cases that providing sample claims submitted to one federal program can suffice. *See Teva Pharms.*, 2016 WL 750720, at *15; *United States ex rel. Kester v. Novartis Pharms. Corp.*, 2015 WL 109934, at *23–24 (S.D.N.Y. Jan. 6, 2015). Such a view may make sense where the particular claims by their nature clearly support an inference of a wide ranging scheme covering multiple programs. *See Kester*, 2015 WL 109934 at *24 (noting that "[t]he sample claims show that false claims were submitted to a half-dozen state Medicaid programs for [three drugs]" while other allegations "provide comparable direct evidence of false claims submitted to Medicare []... for other drugs[]"). But Rule 9(b) does not permit an automatic inference that any allegation regarding the submission of false claims to one program must mean "that false claims were also submitted to" others. *United States ex rel. Chin v. CVS Pharmacy, Inc.*, 2017 WL 4174416, at *8 (C.D. Cal. Aug. 15, 2017) (dismissing State FCA

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⁶ The Government's authority involved parties that had pleaded extremely specific alleged schemes by a few doctors or healthcare facilities, far from the sprawling allegations here. *See United States ex rel. Escobar v. Universal Health Servs.*, 780 F.3d 504, 509, 515 (1st Cir. 2015) (sample claims from two years could support six-year claim about medical treatment provided by four individuals); *United States ex rel. Manion v. St. Luke's Reg'l Med. Ctr., Ltd.*, 2008 WL 906022, at *2–3 (D. Idaho Mar. 31, 2008) (applying the Ninth Circuit's "less stringent test" to avoid requiring pleading "exactly when alleged violations took place over a multi-year time frame" in a case involving alleged billing fraud at three specific hospital locations).

claims related to Medicaid payment under Rule 9(b) despite successful pleading of federal Medicare claims); *see also, e.g., United States v. N. Am. Health Care, Inc.*, 173 F. Supp. 3d 943, 953 (N.D. Cal. 2016) (rejecting argument that Medicaid claims could be inferred from allegations of Medicare claims).

* * *

The Government cannot evade its pleading responsibilities by claiming ignorance. *See* Opp'n 26–27 n.5; *Chorches*, 865 F.3d at 93 (allowing relaxed pleading only if "information about the details of the claims submitted are peculiarly within the opposing party's knowledge"). Indeed, the Second Circuit found a similar pleading failure by the party in possession of claims data to be "particularly not[able]." *United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244, 248 (2d Cir. 2019) (relator worked for the state agency that processed Medicaid claims). If anything, the Government's inability to plead its claims despite a four-year investigation, during which it took wide-ranging discovery, 31 U.S.C. § 3733, warrants dismissal with prejudice. *See United States ex rel. Crennen v. Dell Mktg. LP*, 711 F. Supp. 2d 157, 164 (D. Mass. 2010).

C. The Complaint Does Not Sufficiently Plead that Omnicare Acted "Knowingly."

The Complaint's FCA claims also fail for the independent reason that the Government does not sufficiently allege that Omnicare "knowingly" submitted a false claim or made a false statement. 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B). The Government is incorrect that "scienter need only be pleaded generally," Opp'n 34; in FCA cases the Second Circuit "'ha[s] repeatedly required plaintiffs to plead the factual basis which gives rise to a strong inference of fraudulent intent." *United States ex rel. Tessler v. City of New York*, 712 F. App'x 27, 29 (2d Cir. 2017) (quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)). And the

Supreme Court has made clear that the FCA's intent standard is "rigorous" and must be "strict[ly] enforce[d]." *Escobar*, 136 S. Ct. at 2002.

The Government agrees that it "'does not allege that any Omnicare employee intentionally evaded Omnicare's systems" to cause false claims to be submitted. Opp'n 32 (brackets omitted) (quoting Mot. 17). Instead, the Government suggests that Omnicare's computer-dispensing systems "were *designed* to permit widespread dispensing based on stale, invalid prescriptions." *Id.* The allegations to which it points do not include a single statement about the process by which the computer systems were "designed" or any whiff of an alleged deliberate decision to code defects into the systems. *See* Gov't Compl. ¶¶ 121–141. Indeed, those paragraphs chronicle that Omnicare established various systems to ensure that prescriptions were dispensed pursuant to valid documentation, including coding the systems to allow for rollover prescriptions *only if* the particular long-term-care facility had been designated as a facility to which rollovers were appropriate. This cannot support a finding of recklessness under the FCA, which "entails conduct that is 'highly unreasonable and which represents an extreme departure from the standards of ordinary care." *Grubea*, 318 F. Supp. 3d at 694 (quoting *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996)).

At most, the Government's allegations about the design of Omnicare's systems reflect a view that some specific long-term-care facilities may have been miscoded to allow for rollover prescriptions. The Government's allegations on this point are clouded by its erroneous assumption that, in all states at all times, medication orders were permitted for SNFs only, and that every other kind of long-term-care facility therefore should have been coded to prohibit prescription rollovers. *See*, *e.g.*, Gov't Compl. ¶ 136 (suggesting that facility coding should have been done to reflect that rollovers were allowed in SNFs and prohibited everywhere else).

Because many states permitted rollovers in non-SNF facilities, the Government's suggestion of miscoding reflects, at most, an alleged "need for better quality control" which "does not constitute 'reckless disregard' within the meaning of the FCA." *United States ex rel. Kirk v. Schindler Elevator Corp.*, 130 F. Supp. 3d 866, 879 (S.D.N.Y. 2015); *see also, e.g., United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 110 (3d Cir. 2007) ("The mere failure of a system to catch an error does not establish recklessness.").

The Government cannot claim that Omnicare's employee training on this subject was so inadequate as to constitute recklessness, either. *See* Opp'n 31. The Government did not dispute that it "recognizes that such training *was* in place—it was just conducted at the local level where individuals had direct knowledge of the unique requirements of state law and how each particular facility fit within the relevant state's law." Mot. 18; *see* Gov't Compl. ¶ 106. Accordingly, any mistaken miscoding of a long-term-care facility could not support a finding of recklessness. *See United States ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Grp.*, 298 F. Supp. 2d 91, 101 (D.D.C. 2004) ("Proof of reckless disregard requires much more than errors, even egregious errors.").

The infirmity in the Government's theories of intentional system sabotage and failure-to-train leads it to return repeatedly to the assertion that Omnicare had "knowledge over many years that its pharmacies were dispensing drugs without valid prescriptions." Opp'n 31 (emphasis omitted); see generally id. at 30–34. These statements ultimately refer back to a group of allegations regarding events occurring in discrete Omnicare pharmacies between July 2012 and 2015 in which prescription-documentation issues were allegedly raised to Omnicare supervisors. And although the Government repeatedly references those allegations, it never grapples with Omnicare's arguments as to why they are insufficient. Omnicare argued that many of these

events supposedly showing "knowledge" that Omnicare was committing fraud "occurred in states where the law *permitted* Omnicare's alleged conduct." Mot. 19 (citing Gov't Compl. ¶¶ 200–201, 203–205, 209–210, 213–214, 217, 220). The Government has no response. Omnicare also argued that other of these events were, by the Government's own admission, "resolved" at the local level, while still more were "statements of Omnicare regional compliance officers related to the development of global computer changes" that could not support a finding of intent because they are subsequent remedial measures under Federal Rule of Evidence 407. *See* Mot. 19 & n.9. Again, no response.

When these various irrelevant and defective allegations are cleared out, the Government is left with just a handful of local events occurring at a handful of Omnicare's approximately 160 pharmacies. These events, often pleaded in vague terms and attributed to unidentified "operations managers" or employees with roles related to "compliance," Gov't Compl. ¶¶ 210–211, 216–218, 221, were addressed and, in light of the defects in the rest of the Government's intent theory, using these discrete, resolved events to support a finding of knowledge across Omnicare is improper for the same reason it cannot use its pleadings about the OmniDX Theory to assume the missing allegations from its Oasis Theory: "[A]lleged fraudulent activity at one plant does not constitute an allegation for a different plant." *Jorgenson*, 2007 WL 1287932, at *3.

At minimum, the Government's intent allegations do nothing to support a theory of intent prior to July or August 2012. All of the events on which the Government relies as supposedly giving Omnicare "knowledge . . . that its pharmacies were dispensing drugs without valid prescriptions," Opp'n 31 (emphasis omitted), occurred after that time. And the Government does not dispute that "there is no 'fraud by hindsight.'" *United States ex rel. United Union of Roofers*,

Waterproofers & Allied Workers Local No. 11 v. City of Chicago, 2014 WL 6306582, at *4 (N.D. III. Nov. 12, 2014) (quoting United States ex rel. Garst v. Lockheed–Martin Corp., 328 F.3d 374, 378 (7th Cir. 2003)). The Government relies on four events to reach back into the pre-July 2012 timeframe, none of which provides a plausible basis for intent in that time period:

- Two allegations relate to events allegedly occurring in July 2012 and August 2012, *see* Gov't Compl. ¶¶ 209, 220, which do nothing to establish any knowledge of Omnicare prior to those months.
- Another vaguely asserts "repeated[]" suggestions by an Omnicare employee in Ohio, made at unidentified times during that person's employment, that improper rollovers were occurring. *See id.* ¶ 213. Even if that allegation had identified anything from 2012 or earlier, it is irrelevant because Ohio is one of the many states that *permits* the use of medication orders, making the complained-of rollovers proper under state law.
- The last claims that, at unidentified times between 2006 and 2016, an individual "who consulted with Omnicare pharmacies across the country" informed pharmacies that they had "allowed prescriptions for seniors in Residential Facilities to 'roll over.'" *Id.* ¶ 225. Even if that allegation had identified any such "advice" from 2012 or earlier, there is nothing improper about the fact that Omnicare pharmacies allowed such rollovers—many states permitted just that.

II. THE COMPLAINT DOES NOT STATE A CLAIM AGAINST CVS

The Government separately seeks to hold CVS liable for the same alleged conduct as Omnicare. That claim should be dismissed for all of the reasons stated above, but it should also be dismissed because the Government supplies no basis to sue CVS.

CVS had no relation to Omnicare until an August 2015 acquisition of Omnicare by a CVS subsidiary, and the Government does not even argue that CVS is liable for any conduct occurring before this acquisition.

Even after the August 2015 acquisition, the Government alleges no factual basis to sue CVS. The Government agrees with the general rule "that a parent corporation . . . is not liable for the acts of its subsidiaries," *United States v. Bestfoods*, 524 U.S. 51, 61 (1998), and disclaims any attempt to prove liability through veil piercing, *see* Opp'n 36. And the

Government also agrees that it may hold CVS liable for Omnicare's conduct only if CVS "is directly liable for its own role in the submission of false claims." *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 60 (D.D.C. 2007); *see* Opp'n 34–35. The Government attempts to conjure allegations of such "direct participation" from just 6 paragraphs of its 292-paragraph Complaint, *see* Opp'n 36, but those conclusory allegations do not state a plausible claim for relief against CVS.

One of those allegations is so conclusory it does nothing to "inform [CVS] of the nature of [its] alleged participation in the fraud." *Teva Pharms.*, 2016 WL 750720, at *12; *see* Gov't Compl. ¶ 186 (alleging, devoid of any factual support, that "CVS assumed control over Omnicare's Operations and Compliance departments, overseeing Omnicare pharmacy dispensing practices, policies, and systems"). Two more are group-pleaded allegations CVS addressed in its motion (at p. 5), which the Government does not try to defend. *See* Gov't Compl. ¶ 224 (alleging the content of "a February 2016 draft sales memorandum sent to Omnicare and CVS operations managers"); *id.* ¶ 230 ("Omnicare and CVS had begun in 2015 to address the OmniDX 'rollover' problem.").

The Government's other allegations say nothing about any "direct involvement [by CVS] in the claims process." Opp'n 35 (quoting *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc.*, 2018 WL 4539684, at *5 (D. Mass. Sept. 21, 2018)). A few suggest that a CVS employee may have become aware of the alleged conduct by Omnicare, *see* Gov't Compl. ¶ 8, 186, 201, but the Government does not dispute that "False Claims Act liability has been rejected where a complaint alleged mere knowledge of a claim, rather than any affirmative act by the defendant." CVS Mot. 6 (quoting John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.01[A][2] (4th ed. 2019)). Two other paragraphs assert that—after

Omnicare had solved many of the alleged computer-system defects, *see* Gov't Compl. ¶¶ 227–229—CVS employees suggested further ways that Omnicare might rectify the alleged defects, *see id.* ¶¶ 173, 230. Suggesting that a subsidiary *fix* an alleged computer defect is not "participation in the fraud." *United States v. Teva Pharms. USA, Inc.*, 2016 WL 750720, at *12 (S.D.N.Y. Feb. 22, 2016); *see United States v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 514 (E.D. Pa. 2016) (noting that even a "failure to take steps to end the submission of false claims" by a defendant who knew of them and continued to do business with that party "does not constitute causation under the False Claims Act" (internal quotation marks omitted)).

Rather than defend what it pleaded, the Government again seeks to conjure a new theory of liability that does not appear in its Complaint. It asks the Court to take judicial notice of an October 2016 Corporate Integrity Agreement ("Agreement"), Opp'n 37 n.7, and then to accept a new, undeveloped theory of liability purportedly based on that agreement. Setting aside that the relevance of this Agreement to CVS's potential liability is unclear, and that the Government has not adequately-pleaded a claim post-dating October 2016, see supra Part I.B., the Court should "disregard these theories" because the Government "may not amend a pleading through an opposition brief." Palatkevich v. Choupak, 2014 WL 1509236, at *10 (S.D.N.Y. Jan. 24, 2014). The sole mention of any "Corporate Integrity Agreement" in the Complaint is a vague reference to the existence of "multiple Corporate Integrity Agreements," Gov't Compl. ¶ 120, which does not identify any agreement or explain how one could make CVS liable for Omnicare's alleged conduct. The Government also does not allege a single action by CVS under the Agreement that could constitute "direct involvement [by CVS] in the claims process." Martino-Fleming, 2018 WL 4539684, at *5. Indeed, the only conduct by CVS that the Government alleges occurred after the October 2016 Agreement is that CVS directed Omnicare

to fix whatever supposed system defects remained at that point. See Gov't Compl. ¶¶ 173, 230. Far from reflecting participation in fraud, this conduct is entirely consistent with the Agreement.

III. THE COMPLAINT DOES NOT STATE A "REVERSE" FALSE CLAIM

The Government's separate "reverse false claim" theory is defective for all of the same reasons as its affirmative false claims theory. *See supra* Part I. It also should be dismissed as duplicative and because the Government does not allege any independent payment obligation.

The core allegation on which the Government's reverse-FCA claim is based is that Omnicare obtained funds "for dispensing prescription drugs that were not authorized by valid prescriptions." Gov't Compl. ¶ 285. This is the precise allegation that underlies the Government's affirmative-FCA claim. See id. ¶ 274 (alleging that Defendants "presented false or fraudulent claims for reimbursement for the dispensation of prescription drugs that were not authorized by valid prescriptions and consequently were not eligible for reimbursement."). The law, however, is clear that "[t]he same allegations that state a claim under [affirmative-FCA provisions] cannot also form the basis for a claim under [the reverse-FCA provision]." *United* States v. Mount Sinai Hosp., 256 F. Supp. 3d 443, 458 (S.D.N.Y. 2017) (alteration and citation omitted). The Government cannot paper over this duplication with conclusory allegations that the exact same conduct gave rise to an "obligation" under 31 U.S.C. § 3729(a)(1)(G). See United States ex rel. Integra Med Analytics LLC, 2019 WL 3282619, at *22 (C.D. Cal. July 16, 2019) (rejecting reverse-FCA claim "predicated upon Defendants' statutory obligation to report and return Medicare overpayments" where allegations were "that after overcharging Medicare, Defendants further violated the FCA by failing to return the overpayments."). Although the Government suggests that this rule is an outlier, see Opp'n 41 & n.10, it is well-established within the Second Circuit. See, e.g., United States v. McKesson Corp., 2019 WL 438357, at *11 (E.D.N.Y. Feb. 4, 2019); United States ex rel. Davern v. Hoovestol, Inc., 2015 WL 6872427, at

*9 (W.D.N.Y. Nov. 9, 2015); *United States ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 338 (S.D.N.Y. 2004). And courts across the country "consistently" agree. *United States v. Kinetic Concepts, Inc.*, 2017 WL 2713730, at *13 (C.D. Cal. Mar. 6, 2017).

This fundamental defect in the Government's reverse-FCA pleading cannot be saved as mere pleading "in the alternative under Rule 8." Opp'n 41 n.10. A theory pleaded in the alternative still must state a plausible claim for relief. *Brown v. Kay*, 889 F. Supp. 2d 468, 486 (S.D.N.Y. 2012), *aff'd*, 514 F. App'x 58 (2d Cir. 2013); *see also Nelson v. MillerCoors, LLC*, 246 F. Supp. 3d 666, 679 (E.D.N.Y. 2017) (same "where plaintiffs fail to explain how their unjust enrichment claim is not merely duplicative of their other causes of action.").

Nor did the Government allege the essential element of any reverse-FCA claim—an "obligation" to return an overpayment. *See* 31 U.S.C. § 3729(a)(1)(G).⁷ Despite the Government's suggestion to the contrary, *see* Opp'n 40 & n.9, it cannot base such an obligation on any hypothetical liability that Omnicare may face for the FCA claims in this case. *See United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 505 (3d Cir. 2017) ("obligation" needed to trigger a reverse-FCA claim "does *not* include a duty that is dependent on a future discretionary act"); John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.01 (4th ed. 2020) (2009 amendments to the FCA "contemplate[] only 'present' repayment obligations").

Finally, the Government nods to a statute that defines "overpayment" as "funds that a person receives or retains under subchapter XVIII [governing Medicare] or XIX [governing Medicaid] to which the person, *after applicable reconciliation*, is not entitled" 42 U.S.C. §

⁷ The Government does not assert that it has pleaded the alternate basis for a reverse-FCA claim, which arises if a defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G); see Opp'n 38.

1320a-7k(d)(4)(B) (emphasis added); *see* Opp'n 39. But, as Omnicare argued in its motion—a point to which the Government has no response—the Government makes "no allegation that any such 'reconciliation' occurred." Mot. 23 (quoting *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr.*, 2018 WL 4539684, at *6 (D. Mass. Sept. 21, 2018)). Even if it had, the Government also must allege the "particular circumstances in which Defendants had knowledge of a[n] . . . overpayment that they failed to rectify." *United States ex rel. Forcier v. Comput. Scis. Corp.*, 183 F. Supp. 3d 510, 528 (S.D.N.Y. 2016). The only circumstances the Government alleges that could plausibly apply concern a handful of *resolved* audits by third parties, *see* Opp'n 39–40, but the Government makes no allegation that Omnicare wrongly retained any overpayment identified during the course of those audits. *See* Gov't Compl. ¶¶ 203–205.

IV. THE COMPLAINT DOES NOT STATE A CLAIM FOR UNJUST ENRICHMENT OR PAYMENT BY MISTAKE

The Government's tersely stated claims for "Payment by Mistake of Fact" and "Unjust Enrichment," *id.* ¶¶ 287–292, fail for the reasons the FCA claims do, but they also should be dismissed because the claims do not exist.

The Government abandons any state-law basis for these claims and invokes "federal common law." Opp'n 43. That runs aground on *Erie*'s declaration that "[t]here is no federal general common law." *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). The Government claims authority to make common law on matters related to "the rights and obligations of the United States." Opp'n 42 (citation omitted). That ignores that its own cited cases recognized such authority "[i]n [the] *absence* of an applicable Act of Congress." *United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 726 (1979) (emphasis added); *see also United States v. Kennedy*, 738 F.2d 584, 586 n.3 (3d Cir. 1984) ("In *Kimbell Foods*, the Court's primary concern was

formulating a federal rule in the absence of an existing federal rule.").8

The Government also ignores Omnicare's more recent Supreme Court authority, *see* Mot. 25, which made clear that "[w]hen Congress addresses a question previously governed by a decision rested on federal common law, . . . the need for such an unusual exercise of law-making by federal courts disappears." *Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 423 (2011) (internal quotation marks omitted). This is a far cry from the earlier authorities on which the Government relies, which stated far more lenient standards. *See United States v. Wurts*, 303 U.S. 414, 416 (1938) (allowing federal-common-law claim "unless Congress has clearly manifested its intention to raise a statutory barrier" (internal quotation marks and footnote omitted)); *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 14 (1st Cir. 2005) ("As for displacement of common law, the tests concern whether Congress directly spoke to the issue and whether Congress intended to deprive the government of a longstanding power."); *United States v. Gen. Dynamics Corp.*, 19 F.3d 770, 773 (2d Cir. 1994) ("recovery of subsidies paid by federal government permitted under common law principles in absence of statutory prohibition").

Under the test from *American Electric Power*, Congress has "addresse[d] a question previously governed by a decision rested on federal common law," 564 U.S. at 423, in multiple ways. Medicare and Medicaid permit the Government to recover the allegedly improper payments through audits (which the Government alleges occurred), or through administrative and court proceedings. *See, e.g.*, 42 C.F.R. §§ 405.371, 405.373, 405.375, 405.1803. There is no need for a federal-common-law rule under these circumstances. Whatever need for federal

⁸ The similar statement in *Texas Industries, Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 641 (1981), is supported entirely by citations to earlier decisions making the same point: "In absence of an applicable Act of Congress it is for the federal courts to fashion the governing rule of law according to their own standards." *United States v. Little Lake Misere Land Co.*, 412 U.S. 580, 594 (1973) (quoting *Clearfield Tr. Co. v. United States*, 318 U.S. 363, 366–67 (1943)).

common law there could be absent such remedies, Congress has "addresse[d]" the "question" and "the need for such an unusual exercise of law-making by federal courts disappears." *Am. Elec. Power*, 564 U.S. at 423; *cf. Alexander v. Sandoval*, 532 U.S. 275, 290 (2001) ("The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others.").

That such common-law-making authority has dissipated is especially clear here because the Government is seeking to use federal common law to create an *equitable* claim despite the existence of multiple, adequate *legal* remedies, including those listed above under Medicare and Medicaid, as well as the Government's FCA claim itself. *See United States v. Buckley*, 2005 WL 164287, at *1 (D. Mass. Jan. 25, 2005) ("[T]he equitable remedies sought in Count Three, unjust enrichment and disgorgement, are unavailable as there is an adequate remedy at law."); *accord United States v. Job Res. for Disabled*, 2000 WL 562444, at *4 (N.D. Ill. May 9, 2000); *United States v. Hydroaire, Inc.*, 1995 WL 86733, at *6 (N.D. Ill. Feb. 27, 1995); *United States v. Vector Corp.*, 1994 U.S. Dist. LEXIS 21330, at *16 (N.D. Iowa Apr. 14, 1994).

CONCLUSION

For the foregoing reasons, the Government's Complaint-in-Intervention should be dismissed. Although the Government requested that the Court grant it "[1]eave [t]o [a]mend" to "cure" any deficiencies the Court may identify, Opp'n 45, this request should be denied because the Government does not "explain how [it] proposed to amend the complaint to cure its defects." *F5 Cap. v. Pappas*, 856 F.3d 61, 90 (2d Cir. 2017).

⁹ Prior FCA cases—many of which pre-dated *American Electric Power*—allowing the federal government to bring such claims, *see* Opp'n 42–45, did not grapple with these limitations on federal common law. Nor did this Court's recognition that *State* governments can bring *state* common-law claims give the federal government the much rarer and more circumscribed *federal* common-law authority it now claims. *See United States ex rel. Kester v. Novartis Pharm. Corp.*, 2014 WL 4401275, at *11–12 (S.D.N.Y. Sept. 4, 2014).

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